IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHER DISTRICT OF TEXAS
DALLAS DIVISION

CINDY BURTON,	§	
Plaintiff,	§	
	§	
v.	§	CIVIL ACTION NO.
	§	3:99–CV:0305–G
	§	
WYETH-AYERST LABORATORIES	§	
DIVISION OF AMERICAN HOME	§	ECF
PRODUCTS CORPORATION, ET AL.,	§	
Defendants.	§	

BRIEF IN SUPPORT OF PLAINTIFF'S RESPONSE TO
DEFENDANT WYETH'S MOTION FOR PARTIAL SUMMARY JUDGMENT

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BRIEF IN SUPPORT OF PLAINTIFF'S RESPONSE TO DEFENDANT WYETH'S MOTION FOR PARTIAL SUMMARY JUDGMENT

Plaintiff, Cindy Burton, files this brief in support of her response to Defendant Wyeth's Motion for Partial Summary Judgment, and in support of her request that the motion be denied.

I. Introduction

Wyeth has moved for partial summary judgment on three theories of liability: (1) Ms. Burton's claim of "exercise-induced" pulmonary arterial hypertension (PAH); (2) negligence per se; and (3) conspiracy. As a preliminary matter, Ms. Burton never made a claim for "exercise-induced" PAH. That is Wyeth's term. Wyeth uses the term because Ms. Burton's PAH was diagnosed after her doctor raised her heart rate with mild exertion or exercise. Scores of medical authorities defining PAH prove that this is usual and accepted procedure for diagnosing PAH. The distinction of "exercise-induced" by Wyeth as some **other** disease process is flatly wrong and not accepted or recognized by the medical or scientific

community. Moreover, there are volumes of scientific studies that demonstrate that Wyeth's diet drugs cause PAH—and none of those studies makes the artificial distinction that Wyeth attempts to make in its motion. Because Wyeth's motion is without merit in this regard, the motion for partial summary judgment should be denied.

With regard to negligence *per se* and civil conspiracy—advanced by Ms. Burton's former counsel—Plaintiff Cindy Burton withdraws and abandons those claims.

II. Standard of Review

Under Rule 56, a party is entitled to summary judgment only if it proves that there is no genuine issue of material fact and that it is entitled to prevail as a matter of law. *Strong v. B.P. Exploration & Production, Inc*., 440 F.3d 665, 668 (5th Cir. 2006). This motion, in effect, argues that the movant "is entitled to judgment as a matter of law." *Margolis v. Deason*, 464 F.3d 547, 550 (5th Cir. 2006) (quoting FED. R. CIV. P. 56(c)). If the movant meets the initial burden to show that there is no genuine issue of material fact, "the burden shifts to the nonmoving party to produce evidence or designate specific facts showing the existence of a genuine issue for trial." *Allen v. Rapides Parish Sch. Bd.*, 204 F.3d 619, 621 (5th Cir. 2000). In determining whether there is a genuine issue of material fact, all facts must be evaluated in the light most favorable to the nonmoving party. *Mitusbishi Elec. Indus. Co. v. Zenith Radio Corp*., 475 U.S. 574, 587 (1986). Summary judgment is appropriate only if the nonmovant fails to show the existence of a fact issue on at least one element essential to that party's case. *Piazza's Seafood World, L.L.C. v. Odom*, 448 F.3d 744, 752 (5th Cir. 2006).

III. Argument

A. Introduction

In its motion for partial summary judgment, Wyeth alleges that "exercise-induced" pulmonary arterial hypertension ("PAH") is a "different disease"[1] from *resting* PAH and that, while there might be epidemiological evidence for *resting* PAH, there is no epidemiological evidence to support "exercise-induced" PAH. This is a flawed premise.

Pulmonary hypertension is an increase in the blood pressure in the pulmonary artery (the artery through which the heart pumps blood to the lungs). When secondary causes have be excluded, PAH or PPH[2] is caused by damage to the pulmonary vascular bed (the small arterioles in the lung through which blood is passes and receives oxygen). As these arterioles narrow, they are more resistant to blood flow and thereby cause an abnormally high pulmonary artery pressure.

The method for diagnosing this disease is through a cardiac catheterization. This is a procedure in which the doctor snakes a catheter into the heart (usually through the leg) and takes direct measurements of cardiac hemodynamics, including pulmonary artery pressure. Doctors often measure this pressure while the patient is lying still (at rest) or after raising the patients heart rate through mild exertion (with exercise).

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[1] *See* Wyeth's Brief in Support of Motion for Partial Summary Judgment, at 30.

[2] For the purposes of this motion, Plaintiffs will use the term "pulmonary arterial hypertension," or "PAH", interchangeably with the term "primary pulmonary hypertension," or "PPH"—as the experts in the case do. *See* Deposition of Richard Channick, M.D., April 5, 2005, at 33, attached as Exhibit 9 ("And in my book that's the same as saying the patient likely had PAH.").

If a patient has an abnormally elevated pulmonary artery pressure in either case, then the patient has pulmonary hypertension. Virtually every medical text in the world defines PAH as abnormal pressure at rest or **with** exercise. The medical literature **never** suggests a diagnosis of PAH with exercise is somehow a different disease process. The simple truth is that "exercise-induced" PAH (Wyeth's term) is the **same disease** as resting PAH.

There is voluminous factual and epidemiological evidence that PAH is caused by Wyeth's diet drugs. There is opinion evidence in this case that Cindy Burton's PAH was caused by her ingestion of Wyeth's diet drugs. Wyeth's attempt to reanalyze the epidemiological data in an attempt to manufacture an artificial distinction "does not comport with sound scientific methodology." *See Merrell Dow Pharmaceuticals, Inc. v. Havner*, 953 S.W.2d 706, 720 (Tex. 1997).

Because there remain issues of fact as to whether Cindy Burton's PAH was caused by her ingestion of Wyeth's diet drugs, Wyeth's motion for partial summary judgment should be denied.

B. The History of the Problem

Fortunately, much of the basis of this case has already been studied and analyzed by federal courts. This Court will not be required to re-invent the wheel on a lot of the issues raised here, because those issues have been previously addressed by Judge Bechtle in the MDL. *See Smith v. Wyeth-Ayerst Laboratories Co.*, 278 F.Supp. 684, 701 (W.D. N.C. 2003) ("The Court intends to follow the MDL ruling.").

To understand the issues raised here, it is helpful to briefly review the history of this litigation.

In 1989, Wyeth, formerly known as American Home Products, acquired A.H.Robins and began marketing the drug fenfluramine under the name "Pondimin." *See In re: Diet Drugs*, Civil Action No. 99-20593, MDL Docket No. 1203 (E.D. Pa. August 28, 2000)(hereafter "MDL Litigation"), Memorandum and Pretrial Order No. 1415 (hereafter "MDL Order 1415"), at 6, attached as Exhibit 1.[3] Between 1989 and 1997, Wyeth was responsible for marketing, regulatory compliance, adverse event reporting, safety surveillance and labeling. *Id.* In 1992, an article came out that recommended use of fenfluramine, combined with a drug called phentermine (which was supposed to lessen the side effects of fenfluramine) for weight loss. *Id.* This regimen popularly became known as "Fen-Phen." *Id.* This "Fen-Phen" craze took the nation by storm and Wyeth's sale of its fenfluramine drugs skyrocketed. Wyeth realized that the diet drugs had the potential to make hundreds of millions (if not billions) of dollars in profit.

Another related drug, dexfenfluramine, was developed by Servier in France. *Id.* at 7. In order to protect its blockbuster profits from Pondimin (which was coming off patent protection in 1994), Wyeth acquired the rights to market dexfenfluramine, which it did under the name "Redux" from June 1996 to September 1997. *Id.* Wyeth's scheme was to tell everyone that this drug provided the same anorexic effects as Pondimin, without the need to add phentermine. *Id*. In fact, Redux was simply an isomer of Pondimin (the active half of the same molecule).

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[3] On January 2, 2007, Wyeth filed six voluminous motions. Because many of the issues raised in those motions overlap, and for the convenience of the Court, Plaintiff has organized all of the exhibits that respond to all of the motions into one appendix, entitled Appendix of Exhibits For Plaintiff's Responses to Wyeth's January 2, 2007 Motions (hereafter "Appendix"). All references to Exhibits will be to the exhibits contained and listed in that Appendix.

During this period, Wyeth knew that its drugs could cause serious heart valve damage and could cause the serious and potentially fatal disease PPH (PAH).[4] Wyeth knew that its label had no warning for the risks of valvular heart disease and a wholly inaccurate statement regarding PPH. *Id*. Wyeth studied the effect that a proper label design (such as a "black box" warning)—designed to make physicians aware of the danger of PPH—would have on sales.[5] Wyeth then did everything it could to avoid putting a strong warning on its diet drugs.[6] Wyeth engaged in a campaign to downplay the known risks of the diet drugs, including instructing its sales force to avoid bringing up the PPH risk with physicians and then to mislead the physicians when it did come up.[7] Wyeth tried to "neutralize" leading experts on PPH when they spoke out about the risks. *See* Exhibits 6 and 33. Wyeth spent large amounts of money to have physicians ghost write articles actually authored or edited

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[4] Despite Wyeth's knowledge of serious health risks, it failed to change its label or report the information to the FDA. *See* Exhibit 1, MDL Order 1415, at 8; *see also* Generic Expert Report of John L.Gueriguian, M.D. On Behalf of Plaintiffs (hereafter "Gueriguian Report"), filed in MDL Litigation, April 14, 2000, at 8, attached as Exhibit 2. Wyeth not only knew about serious risks of patients contracting valvular heart disease, but also it knew about serious risks of developing primary pulmonary hypertension (PPH). *See* Exhibit 2, Guerigian Report, at 7. Despite the knowledge (by 1996) that there were over 200 cases of PPH, with at least 64 deaths, Wyeth's label read, in the "precautions" section, that there were four cases of PH, but the condition appeared reversible. *Id.*.

[5] Wyeth's own documents show that it knew that "Price and PPH are the key product attributes that impact physicians' and managed care's willingness" to prescribe its diet drugs. *See* Exhibit 28, Wyeth's Internal Correspondence of March 29, 1995. The company knew that "sales potential decreases by as much an one-half, if there is a PPH warning." *Id*; *see* Exhibit 29, Wyeth's Internal Correspondence of November 21, 1995 ("a black box for PPH … would be an extremely strong negative"); *see* also Exhibit 30, Wyeth's Internal Correspondence, April 7, 1995.

[6] "Every attempt will be made to ensure that no black box warnings, restrictions of use or negative statements find their way into the redux labeling…. We will make every effort to neutralize these initiatives." *See* Exhibit 31, Wyeth's Internal Correspondence of November 22, 1995.

[7] For example, Wyeth sent a memorandum to its Texas sales force stating "the PPH possibility should not be brought up unless you are specifically asked a question on it by the physician. When it is brought up, you should put it in proper perspective by describing the where the information came from and the controversy surrounding whether or not there is even a direct correlation to anorectics." *See* Exhibit 32, Wyeth Memo, August 8, 1996.

by Wyeth's employees or agents. *See* Exhibit 18. Finally, Wyeth destroyed adverse event reports of cardiac side effects of these drugs that it was required to report to the FDA.[8]

By 1997 Wyeth could no longer conceal the truth about the serious risks of valvular heart disease. Mayo Clinic researchers observed and reported an association between fenfluramine and dexfenfluramine and valvular heart disease in March, 1997, and the FDA requested withdrawal of the drugs from the market. *See* Exhibit 1, MDL Order 1415, at 8-9. On September 15, 1997, Wyeth and the FDA announced that there would be no further sales of the drugs. *Id*. at 9. The "products were found to be unsafe [and] may not be compounded." 21 C.F.R. §216.24.

C. Well-settled Epidemiological Evidence Demonstrates That Use of Fenfluramine And Dexfenfluramine Causes PAH

It can no longer be doubted that there is sufficient epidemiological evidence to demonstrate that use of the diet drugs, fenfluramine and dexfenfluramine, can cause PAH. Judge Bechtle found that "[t]wo well done epidemiological studies establish that the use of fenfluramine and dexfenfluramine cause PPH." *See* Exhibit 1, MDL Order 1415, at 40-41.

[8] In fact, Wyeth was cited by the FDA for "overwriting" 14 files of adverse reports of valvular disease that were required to be reported to the FDA, and "losing" the 14 physical files that contained the reports from the Mayo Clinic. *See* Exhibit 3, at 21-25, FDA Citation, September 10, 1997. A Wyeth internal memorandum indicates that Wyeth's Drs. Davis and Constantine, two of Wyeth's officers, ordered the adverse report files overwritten. *See* Exhibit 4, Wyeth Memorandum from Mary Frances Moeller, dated March 12, 1997.

Those two studies are the International Primary Pulmonary Hypertension Study (IPPHS)[9] and the Surveillance of North American Pulmonary Hypertension (SNAPH).[10] *Id.* at 41.

Both studies exceed the requirements for admissible evidence of causation stated in *Merrell Dow Pharmaceuticals, Inc. v. Havner*, 953 S.W.2d 706 (Tex. 1997). To establish causation, *Havner* requires a doubling of the relative risk factor for those exposed to the causative agent, a 95% confidence level with a confidence interval that does not include the number 1.0. *Id.* at 716-18, 721, 723-24. IPPHS found a 6.3 to 1 relative risk, a 95% confidence level, at a confidence interval of 3.0 to 13.2. *Id.* ; *see also* Affidavit of Harold Palevsky, M.D., at 3, attached as Exhibit 7. The 6.3 to 1 risk means that diet drug users are 630 times more likely to suffer PPH as non-users. SNAP found a 7.5 to 1 relative risk, a 95% confidence level, at a confidence interval of 1.7 to 32.4.[11]

That this causation finding is not doubted is shown in the recent deposition of Wyeth's expert, Dr. Steven Koenig. Dr. Koening admitted that he had diagnosed patients with PPH caused by use of diet drugs:

> Q. So in this over a hundred case that you've looked at, have you ever reached the conclusion that the patient had pulmonary hypertension caused by diet drugs?
>
> A. Yeah, I have.

[9] The IPPHS study is attached as an exhibit to the Affidavit of Dr. Harold Palevsky. *See* Exhibit 7, at Burton Appendix 360.

[10] The SNAPH study is also attached as an exhibit to the Affidavit of Dr. Harold Palevsky. *See* Exhibit 7, at Burton Appendix 369.

[11] *Id.*, at 369.

See Deposition of Steven M. Koenig, M.D., December 18, 2006, at 46, 101, attached as Exhibit 8.

D. Cindy Burton Suffers From Pulmonary Hypertension

Cindy Burton used fenfluramines (Pondimin and Redux) for approximately a year. *See* Exhibit 7, Dr. Palevsky Affidavit, at 5. Following her use of diet drugs, Ms. Burton contracted pulmonary hypertension. *Id.* No one disputes this. Wyeth's expert, Dr. Koenig, acknowledged that Ms. Burton suffered from pulmonary hypertension, and that it would be "wrong to state" that she does not. *See* Exhibit 8, Dr. Koenig Depo., at 101.

E. Cindy Burton's Pulmonary Hypertension Fits Within The Universally-Accepted Definition of Pulmonary Arterial Hypertension

Here is where the rubber meets the road with regard to Wyeth's motion for partial summary judgment. In its motion for partial summary judgment, Wyeth attempts to create an artificial distinction between "exercise-induced" PAH and "resting" PAH, as if they were different diseases. Wyeth has presented no scientific literature or studies that ever made such a distinction. Instead, Wyeth is attempting to parse the data in the accepted studies in an effort to manufacture a distinction that no one in the medical or scientific community recognizes. Such attempts to reanalyze data have been rejected. *See Havner*, 953 S.W.2d at 720 ("an expert cannot dissect a study, picking and choosing data, or 'reanalyze' the data" if the process "does not comport with sound scientific methodology.").

Contrary to Wyeth's theory in its motion for summary judgment, the medical and scientific community universally recognizes that PAH diagnosed on "exercise" is just as much PAH as resting PAH. They **are not** different diseases. *See* Exhibit 7, Dr. Palevsky

Affidavit, at 3 ("While exercise-associated pulmonary hypertension represents the earliest phase possible to diagnose pulmonary vascular disease, it in no way implies different pathogenesis.").

Cindy Burton's disease fits within the universally accepted definition of PAH. In the MDL Litigation, Judge Bechtle explained:

> The community of physicians with expertise in diagnosing and treating PPH have repeatedly reached a consensus concerning the appropriate criteria for diagnosing and defining the disease. This consensus was expressed at the World Health Organization meeting in 1973, in a statement of the American College of Chest Physicians in 1993 and in the Executive Summary of the World Symposium on Primary Pulmonary Hypertension in 1998. In addition, this 'consensus definition' of PPH has been expressed in every major epidemiological study concerning the disease that has ever been done.

Exhibit 1, MDL Order 1415, at 39. Dr. Palevsky noted that this same "consensus definition" is "universally accepted by physicians throughout the world in texts, in peer review journal articles, and in organization statements. *See* Exhibit 7, Dr. Palevsky Affidavit, at 2 (attaching texts, peer review journal articles and organization statements that rely on definition).

Judge Bechtle set out the "consensus definition" of PPH as follows, quoted in relevant part:

> The consensus defining and diagnosing PPH has three elements. The first of the three criteria necessary to make a diagnosis of primary pulmonary hypertension is a mean artery pressure $\geq$ 25 mm Hg at rest or $\geq$ 30 mm Hg **with exercise** as measured at cardiac catheterization.

Exhibit 1, MDL Order 1415, at 39 (emphasis added).

The universality of this definition is shown by the fact that both of Wyeth's experts, in their expert reports, state that the "accepted hemodynamic criteria" for a diagnosis of PAH

includes a diagnosis of "30 mm Hg **with exercise** . . ." *See* Report of Hunter Clay Champion, M.D., at ¶9, at 2 (emphasis added), attached as Exhibit 10; Amended Report of Stephen [sic][12] Koenig, M.D., at ¶11, at 4, attached as Exhibit 11. Further, Wyeth accepted that definition as the proper definition of PPH in the Nationwide Class Settlement. *See* Nationwide Class Settlement Agreement with American Home Products (As Amended), dated November 18, 1999, at ¶I(46), at 8, attached as Exhibit 12.

Without dispute, Cindy Burton fits within this "consensus definition" of PPH. Wyeth's expert Dr. Koenig reports that "[c]ardiac catheterization is the gold standard for diagnosing cardiopulmonary diseases such as pulmonary hypertension." *See* Exhibit 11, Koenig report, at ¶25, at 8. In many places in this record, Cindy Burton's medical reports concerning her catheterizations are reported, including in the Affidavit of Dr. Palevsky. *See* Exhibit 7, at 4. Dr. Palevsky notes that cardiac catheterizations on done in 2002, 2004 and 2006 revealed that Cindy Burton's mean pulmonary artery pressure exceeded 30 mm Hg with exercise—in some reports as much as 50 mm Hg—which placed her within the "consensus definition" of PAH. *Id.* at 7-8.

Under the approved definition, Cindy Burton's "exercise diagnosed"[13] PAH is just as much PAH as "resting diagnosed" PAH. It is just as improper to say that there is no evidence to support "exercise diagnosed" PAH as it would be to say that there was no evidence of

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[12] The correct name of Wyeth's expert is "Steven" Koenig.

[13] Wyeth does not point to any study or scientific literature that ever referred to someone who is diagnosed with PAH on exercise as having "exercise-induced" PAH. This artificial construct appears to be a deliberate misnomer because the exercise does not "induce" the PAH; rather, the exercise is what permits the physician to diagnose the already existing PAH. Instead of Wyeth's artificial construct, Dr. Palevsky uses the term "exercise associated" PAH. *See* Exhibit 7, at 2-4. It would, perhaps, be more correct, to refer to her condition as "diet drug-induced" PAH.

studies concerning patients who were diagnosed on Thursdays. It is improper to try to reanalyze the data by carving out subsets. *See Havner*, 953 S.W.2d at 720.

F. Reliable Evidence Shows That Cindy Burton's PAH Was Caused By Her Ingestion of Diet Drugs

To show that there is reliable evidence of causation, a person must show a peer-reviewed epidemiological study that meets the accepted criteria for doubling of the risk and confidence level. *See Havner*, 953 S.W.2d at 723-24. In this case, two well-respected peer-reviewed studies—the IPPHS and SNAPH—have found that PPH/PAH is caused by the use of Wyeth's diet drugs, in studies that exceed the risk and confidence levels required by *Havner*. There is no dispute that Cindy Burton fits within the criteria of that study in terms of duration and dose.[14] *Id.* at 720. Those studies "definitely settled the question of a causal connection between anorectic drugs and PPH." *See* Exhibit 7, Dr. Palevsky Affidavit, at 3.

Thus, under *Havner*, Cindy Burton has presented sufficient epidemiological evidence to go to the jury on liability.

Wyeth asks this Court to disagree with the conclusion of those studies. Wyeth says that those studies were done of "resting" PAH, and therefore, the authors of those studies' conclusions that use of anorexic drugs causes PAH means only that it causes "resting" PAH. The authors did not say that. They concluded that the use of anorexic drugs causes PAH. Within the accepted definition, Cindy Burton has PAH caused by her use of diet drugs. Once again, Wyeth cannot "reanalyze" or "dissect" the study in order to arrive at a different

[14] Ms. Burton used Wyeth's diet drugs for a year. *See* Exhibit 7, Dr. Palevsky Affidavit, at 4.

conclusion than the authors. *See Havner*, 953 S.W.2d at 720; *Missouri Pac. R.R. v. Navarro*, 90 S.W.3d 747, 757 (Tex. App.—San Antonio 2002, no pet.).

Wyeth contends that Dr. Channick stated that he could not determine the cause for Cindy Burton's "exercise-induced" PAH. That is not so. Dr. Channick, who is one of the leading specialists in PPH in the world,[15] stated "I believe that she has pulmonary arterial hypertension associated with her prior ingestion of anorexigen drugs." *See* Deposition of Richard Channick, M.D., November 1, 2006, at 225-26, attached as Exhibit 13. In fact, Dr. Channick expressly rebutted Wyeth's contention that "exercise-induced" PAH is not supported by epidemiological evidence.

> Q. You were asked whether there were specific studies that parsed out and studied only the subset of pulmonary hypertension on exercise cases versus resting pulmonary hypertension associated with diet drugs. Do you remember that question?
>
> A. Yes.
>
> Q. Okay. Would you agree with me that Ms. Burton meets the definition of someone who has pulmonary hypertension?
>
> A. Yes.
>
> Q. And would you agree with me that . . . there's ample epidemiological evidence to demonstrate that there is an increased risk of contracting pulmonary hypertension associated with the use of fenfluramines?
>
> A. That's correct

Exhibit 13, Channick Depo., at 247-48).

[15] *See* Curriculum Vitae of Richard Neil Channick, M.D., FCCP, attached as Exhibit 14

Dr. Harold Palevsky, also recognized throughout the world for his work with PPH—he has been lecturing, writing and researching PPH since 1984[16]—concurs. He states: "Based upon the known causes of PAH, the exclusion of other causes and conditions, the documented use of fenfluramines, the diagnostic studies and observation described in the medical records and above, Ms. Burton's exercise associated PAH was, within a reasonable degree of medical certainty, caused by fenfluramines." *See* Exhibit 7, Dr. Palevsky Affidavit, at 5.

Thus, there is no merit to Wyeth's contention that there is no reliable evidence that Cindy Burton's PAH was caused by her use of Wyeth's diet drugs. Because Wyeth has failed to show that it is entitled to judgment as a matter of law on this point, and because fact issues remain, the motion for partial summary judgment should be denied.

CONCLUSION

For the above reasons, Wyeth's motion for partial summary judgment should be denied.

[16] *See* Curriculum Vitae of Harold Ingram Palevsky, M.D., attached as Exhibit 15.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on February 8, 2007, I electronically submitted the foregoing document with the clerk of court for the U.S. District Court, Northern District of Texas, using the electronic case files system of the court. The electronic case files system sent a "Notice of Electronic Filing" to the following individuals:

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